AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,806	05/04/2001	Jen Sheen	00786/389002	7904

21559 7590 02/09/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,806	SHEEN, JEN	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November18, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *9 and 17-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November18, 2005 has been entered.

Claims 1-57 are pending.

Claim 1 is currently amended.

Claims 9 and 17-53 are withdrawn.

Claims 1-8, 10-16 and 54-57 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-7, 10-16, 54 and 56 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

Applicant's arguments filed November 18, 2005 have been fully considered but they are not persuasive.

Applicant notes that the molecules useful in practicing the claimed methods do not differ radically from each other and the examples found in the specification identify the group broadly to the skilled worker, and maintains therefore that the recitation of calcium dependent protein kinase (CDPK) is therefore sufficient to satisfy the written description requirement. (reply page 10)

The Examiner maintains that merely saying that the nucleic acid molecules encode a polypeptide having calcium dependent protein kinase activity does not describe the nucleic acid molecules required to practice the claimed invention, because the genus of nucleic acid molecules required to practice the claimed invention is not adequately described. See *University of California v. Eli Lilly,* 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), where it states:

> naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. *See Fiers,* 984 F.2d at 1171, 25 USPQ2d at 1606.

Applicant also points out that the case law is clear that it is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every species, and maintains that specification and examples, which teach how to select and use CDPK DNAS, are adequate to show those skilled in the art how the claimed invention is to be practiced. (reply page 10)

The Examiner maintains that the outstanding rejection was not predicated on a failure to give an example of every species falling within the claimed genus, or on a failure to name to name every species. The outstanding rejection was predicated on a failure to describe a representative number of species falling within the scope of the claimed genus. The specification describes only two sequences encoding calcium dependent protein kinases obtained from a single plant species, CDPK2 (SEQ ID NO:2) and CDPK4 (SEQ ID NO:4), which encode polypeptides (SEQID NOS: 1 and 3) that have 95% sequence identity to each other. This does not constitute a substantial portion of the genus required to practice the claimed method, which encompasses nucleic acid molecules obtained from any source that encode polypeptides having at least 80% identity to SEQ ID NO:1.

The Examiner also maintains that whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case, while the specification provides a process for selecting and using CDPK DNAs, there is no further information in the specification pertaining to the relevant structural or physical characteristics of these CDPK DNAs; in other words, it thus does not describe CDPK DNAs encoding polypeptides having at least 80% identity to SEQ ID NO:1 and calcium dependent protein kinase activity. Further, describing methods for selecting and using CDPK DNAs does not necessarily describe the amino acid sequences of the CDPK polypeptides having at least 80% identity to SEQ ID NO:1.

With respect to the ground of rejection that the specification does not describe the specific structural features of SEQ ID NO:1 that are correlated with its function of increasing the level of resistance to a disease-causing pathogen, Applicant points out that the CDPK sequences used in the claimed methods encode CDPK polypeptides, and maintains that calcium dependent protein kinase activity is clearly a functional limitation that distinguishes the polypeptides used in the methods from other polypeptides. Applicant also points to the Written Description Guidelines, which detail, functional characteristics alone or coupled with a known or disclosed correlation between structure and function among the factors to be considered in determining whether there is sufficient evidence of possession, and Applicant maintains that the nucleic acids used in the claimed methods encode polypeptides that are distinguished from other polypeptides on the basis of having at least 80% identity to SEQ ID NO:1 and calcium dependent protein kinase activity. (reply pages 10-11)

The Examiner maintains that a showing of possession alone is not sufficient to describe the claimed invention. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

> Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

In the instant case, while the functional characteristic of calcium dependent protein kinase activity alone may be evidence of possession, the functional characteristic of calcium dependent protein kinase activity alone does not describe the structure of nucleic acids that encode calcium dependent protein kinase polypeptides that have at least 80% identity to SEQ ID NO:1.

Applicant also points out that it is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention." See Capon v. Eshhar, 418 F.3d 1349,1359 (Fed.Cir.2005), citing In re Angstadt, 537 F.2d 498,504 (CCPA 1976), and that no evidence currently made of record in this case questions the enablement of applicant's claimed invention. Moreover, applicant notes that identifying inoperable nucleic acid molecules encoding CDPK polypeptides is accomplished using routine screening methods known in the art when the application was filed, that the disclosure provides considerable direction and guidance on how to practice their invention and presents working examples, aiding the skilled worker to weed out inoperable constructs, that there was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known. Applicant maintains that the specification clearly characterizes the claimed generic method, and

that any experimentation needed to practice the invention would not be considered undue. (reply pages 11-12)

Applicant's arguments directed to enablement are inapposite to the outstanding rejection, which was made under 35 U.S.C. 112, first paragraph, for lack of written description. The Examiner maintains that there is NO outstanding rejection under 35 U.S.C. 112, first paragraph, for lack of enablement.

Claim Rejections - 35 USC § 102

Claims 1-8, 10-16 and 54-57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998), for the reasons of record.

Applicant's arguments filed November18, 2005 have been fully considered but they are not persuasive.

Applicant maintains that the rejection should be withdrawn in light of the amendment of claim 1 to require "introducing a transgene that overexpresses a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide into a plant cell that is susceptible to a disease-causing pathogen." Applicant points out that WO 98/26045 is silent on whether CDPK regulates disease resistance genes, and maintains that there is no evidence indicating that disease resistance is necessarily present. Applicant also points out that WO 98/26045 is silent on introducing a transgene into a plant cell that is susceptible to a disease-causing pathogen, as required by the claims. (reply page 12)

Applicant's arguments are unconvincing. The fact that WO 98/26045 is silent on whether CDPK regulates disease resistance genes, and the fact that that there is no evidence indicating

that disease resistance is necessarily present, does not overcome the rejection, as the specific effect is presumed to be mediated by an inherent function of the CDPK polypeptide expressed in the plant cell. Furthermore, addition of the limitation that the plant cell "is susceptible to a disease-causing pathogen" also does not overcome the rejection, as any plant cell is inherently susceptible in some way to some plant pathogen, and the plants species disclosed by Sheen (cruciferous plants, maize and tomato, for example) are known to be susceptible to plant pathogens.

See *Integra Life Sciences I Ltd. v. Merck KGaA,* 50 USPQ2d 1846 (DC SCalif, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products. See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

The rejected claims recite no technical features that distinguish Applicant's claimed method from the method taught by Sheen, and the claimed method relies on the use of compositions (calcium dependent protein kinase and plant cell that is susceptible to a disease-causing pathogen) that are distinguished from the prior art compositions on the basis of inherent functional characteristics. Accordingly, the claimed invention is anticipated by the prior art reference.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
2/6/06